

**Translation**

**PATENT COOPERATION TREATY**

**PCT**

**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|  |   |   |
|--|---|---|
| Applicant's or agent's file reference<br><b>S27F1389</b>   | <b>FOR FURTHER ACTION</b>                                       | See Form PCT/IPEA/416                               |
| International application No.<br><b>PCT/JP2004/011275</b>  | International filing date (day/month/year)<br><b>05.08.2004</b> | Priority date (day/month/year)<br><b>20.08.2003</b> |
| International Patent Classification (IPC) or national classification and IPC<br><b>C08F261/04, A61K9/32, A61K47/32, A23L1/00</b> |   |   |
| Applicant<br><b>SHIONOGI &amp; CO., LTD.</b>   |   |   |

|  |                                   |
|--|-----------------------------------|
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>4</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |                                   |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>   |                                   |
| Date of submission of the demand   | Date of completion of this report |
| Name and mailing address of the IPEA/JP  | Authorized officer                |
| Facsimile No.  | Telephone No.                     |

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/011275

Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-3, 5-16 as originally filed/furnished
- pages\* 4 received by this Authority on 27.04.2005
- pages\* 4/1 received by this Authority on 07.09.2005
- ☒ the claims:
- nos. 1-16 as originally filed/furnished
- nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19
- nos.\* 18, 19 received by this Authority on 27.04.2005
- nos.\* 17 received by this Authority on 07.09.2005
- ☒ the drawings:
- sheets 1/3-3/3 as originally filed/furnished
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/011275

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

|                               |        |             |     |
|-------------------------------|--------|-------------|-----|
| Novelty (N)                   | Claims | 14, 15, 19  | YES |
|                               | Claims | 1-13, 16-18 | NO  |
| Inventive step (IS)           | Claims |             | YES |
|                               | Claims | 1-19        | NO  |
| Industrial applicability (IA) | Claims | 1-19        | YES |
|                               | Claims |             | NO  |

## 2. Citations and explanations (Rule 70.7)

Claims 1 to 13 and 16 to 18 lack novelty and do not involve an inventive step in the light of documents 1 to 3, indicated below.

Document 1 discloses a polyvinyl alcohol-based resin that has a degree of saponification of between 93.0 and 99.9 mol% and a degree of polymerization of between 500 and 2000, and further presents a mixture that comprises an ethyl acrylate, a methyl methacrylate and an acrylic acid as an example of a monomer mixture that can be polymerized in the presence of said polyvinyl alcohol-based resin (example 4).

Therein, the composition disclosed in document 1 comprises 40 to 200 parts by weight of a polyvinyl alcohol resin in relation to 100 parts by weight of the copolymer composition, and thus the ratio of the polyvinyl alcohol resin to the vinyl monomers falls within a range of approximately 3 : 7 to 7 : 3.

Document 2 discloses a composition which comprises 0.2 to 30.0 parts of a polymerizable vinyl monomer that contains carboxyl groups per 100 parts of the PVA, as well as 0.2 to 30.0 parts of a polymerizable vinyl monomer that is capable of reacting with carboxyl groups so as to form chemical bonds per 100 parts of the PVA.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2004/011275

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

Therein, document 2 also indicates that 5 to 80% by weight of the polymerizable vinyl monomers are (co) polymerized in the presence of 20 to 95% by weight of a polyvinyl alcohol and/or a derivative thereof (claims 1 and 7).

Claims 14, 15 and 19 do not involve an inventive step in the light of documents 1 and 4.

Document 4 discloses a feature wherein a coating composition that comprises a polyvinyl alcohol as a base agent is used to coat medicaments, food products and the like. As a result, it would have been easy for a person skilled in the art to conceive of likewise using the polyvinyl alcohol-based coating composition that is disclosed in document 1 in order to coat medicaments, food products and the like.

## Prior Art Documents

Document 1: JP 2002-105383 A (Saiden Chemical Industry Co., Ltd.), 10 April 2002

Document 2: JP 60-255811 A (Teikoku Chemical Industries Co., Ltd.), 17 December 1985

Document 3: WO 02/017848 A1 (Nisshin Kasei Co., Ltd.), 07 March 2002

Document 4: JP 2003-509339 A (Berwind Pharmaceutical Services, Inc.), 11 March 2003

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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## Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The amendments dated 07 September 2005 amend claim 17 so as to add the disclosure "do not include a copolymer of a polyvinyl alcohol and a polymerizable vinyl monomer that is capable of reacting with carboxyl groups so as to form chemical bonds" and the disclosure "do not include a copolymer of a polyvinyl alcohol that has an average degree of polymerization of between 1500 and 1700 and an unsaturated carboxylic acid, a salt thereof or an ester of the unsaturated carboxylic acid" thereto.

However, the features in question are not disclosed in the description that was submitted when the application was originally filed.